

A. Yaccarino as an inventor (Yaccarino being an inventor of the present application) and United States Patent Number 6,025,538 of which the present application is a continuation-in-part added David C. Paul as an inventor (Exhibit B). The present application may have to add David C. Paul as an inventor depending on the final language of the claims. Figures 7, 8, 8A and 11 in the '125 patent on which the Examiner's argument were based are substantially taken from a device and drawings made by Joseph Yaccarino prior to the filing of the provisional application number 60/095,209 on August 3, 1998 from which the 6,258,125 patent claims priority. Figures 7, 8, 8A and 11 also basically appear in U.S. Letters Patent 6,025,538 issued February 15, 2000 as Figures 10, 11 and 12 (Exhibit C), the parent case of this present application. The '538 patent was filed November 20, 1998 prior to the July 10, 2001 <sup>Declar</sup> filing date of the '125 patent but after the August 3, 1998 filing date of the provisional application upon which the '125 patent claims priority. See the attached Exhibits noting the addition of inventorship as noted above and comparison of the drawings. Thus, the subject matter relied upon by the Examiner in the '125 patent rejecting the present application is the invention of an inventor in the present case filed before the filing date and issuance of the '125 patent bearing a common inventor. Therefore, the '125 patent is not a valid reference. The other figures of the '125 patent and descriptions of same do not obviate the present invention. Applicant will file a Declaration under 37 CFR 1.131 and 37 CFR 1.132 with respect to the 6,258,125 patent.

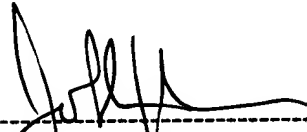
United States Patent Number 5,968,047 to Reed discloses a number of bone screws, pins, anchors and plates fabricated from bone tissue. There is no teaching of the fasteners in this reference using a fastener to hold two or more bone members together to form a compound bond device for implantation into a surgical site to support an anatomical load applied to the device during a post operative period. Indeed, Reed '047 is used at a fracture site to screw bone pieces together or a plate to a bone fracture area. There is no teaching of a load bearing device.

Formal drawings including Figure 6 through 16 have been simultaneously submitted by a Transmittal of Formal Drawings which has been separately filed. An Extension of Time for three (3) months together with fee has also been filed with this Agreement.

It is respectfully requested that the arguments in the present application place the application in condition for favorable reexamination and that the application be passed to issue.

Respectfully submitted,

GIPPLE & HALE

A handwritten signature in black ink, appearing to read 'John S. Hale', is written over a horizontal dashed line.

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## **CLEAN SET OF CLAIMS REMAINING IN APPLICATION**

Claim 1. A compound bone device made from sterile bone tissue for implantation into a surgical site which supports an anatomical load applied to the compound bone device during a post-operative period while the implanted bone tissue is being resorbed and remodeled, comprising:

a first bone member defining a first mating face with a plurality of spaced projections constructed and arranged to support a load in a direction that is normal to the first mating face and to receive and engage a complimentary mating face of a second bone member;

a second bone member defining a second mating face that is complimentary to the first mating face of the first bone member constructed and arranged to support a load in the direction normal to the second mating face, said mating faces being mounted to each other so that the first and second bone members form a compound bone device which prevents displacement of the first bone member with respect to the second bone member in both a longitudinal direction and a transverse direction when an anatomical load is applied;

each bone member defining at least one bore within its body having an axis which intersects a plane across its mating face with said bore opening on said mating face, each bore being axially aligned with a bore defined in the body of an adjacent bone member and a threaded fastener member mounted in said axially aligned bores and extending across said mating face threadably engaging at least one of said bone members to hold the first and second bone members in engagement resisting separation of the first and second bone members.

Claim 2. A compound bone device made from bone tissue as claimed in Claim 1 wherein each bone member has a body which defines at least two angularly positioned bores which are axially aligned with the angularly positioned bores of an adjacent bone member, said bores being orientated at an oblique angle to a plane of each engaged mating surface and intersecting the plane of the mating surface and a threaded fastener member is mounted in each of the aligned bores.

**Claim 3.** A compound bone device made from bone tissue as claimed in Claim 1 wherein said threaded fastener member is a screw.

**Claim 4.** A compound bone device made from bone tissue as claimed in Claim 1 wherein said threaded fastener member is a threaded bolt.

**Claim 5.** A compound bone device made from bone tissue as claimed in Claim 1 wherein said threaded fastener member is a threaded rod.

**Claim 6.** A compound bone device made from bone tissue as claimed in Claim 1 wherein said threaded fastener member is a threaded rod with at least one nut member.

**Claim 7.** A compound bone device made from bone tissue as claimed in Claim 1 wherein said threaded fastener member is a threaded bolt with an associated nut member.

**Claim 8.** A compound bone device made from bone tissue as claimed in Claim 1 wherein one of the mating faces defines a plurality of bar members substantially parallel to the longitudinal axis of bone members and a plurality of bar members oriented transverse to the axis of the parallel bar members.

**Claim 9.** A compound bone device made from sterile bone tissue for implantation into a surgical site which supports an anatomical load applied to the compound bone device during a post-operative period while the implanted bone tissue is being resorbed and remodeled, comprising:

a first bone member defining a first mating face constructed and arranged to support a load in a direction that is normal to the first mating face and to receive and engage a complimentary mating face of a second bone member;

a second bone member defining a second mating face that is complimentary to the first mating face of the first bone member constructed and arranged to support a load in the direction

normal to the second mating face, said mating faces being mounted to each other so that the first and second bone members form a compound bone device which prevents displacement of the first bone member with respect to the second bone member in both a longitudinal direction and a transverse direction when an anatomical load is applied;

each bone member defining at least one throughgoing bore within its body which opens on said mating face and has a stepped countersink portion at its opposite end, each bore being axially aligned with an angularly oriented bore defined in the body of the other bone member and a threaded fastener member mounted in said axially aligned bores extending across said mating face to hold the first and second bone members in engagement resisting separation of the first and second bone members.

Claim 10. A compound bone device made from bone tissue as claimed in Claim 9 wherein said threaded fastener member is a bolt and nut assembly.

Claim 11. A compound bone device made from bone tissue as claimed in Claim 9 wherein said threaded fastener member is a threaded rod with at least one nut member.

Claim 12. A compound bone device made from bone tissue as claimed in Claim 9 wherein each bone member has a body which defines at least two angularly positioned bores which are axially aligned with the angularly positioned bores of an adjacent bone member, said bores being orientated at an oblique angle to a plane of each engaged mating surface and intersecting the plane of the mating surface and a threaded fastener member is mounted in each of the aligned bores.

Claim 29. A compound bone device made from sterile bone tissue for implantation into a surgical site which supports an anatomical load applied to the compound bone device during a post-operative period while the implanted bone tissue is being resorbed and remodeled, comprising:

a first bone member defining a first mating face constructed and arranged to support a load in a direction that is normal to the first mating face and to receive and engage a complimentary mating face of a second bone member;

a second bone member defining a second mating face that is complimentary to the first mating face of the first bone member constructed and arranged to support a load in the direction normal to the second mating face, said mating faces being mounted to each other so that the first and second bone members form a compound bone device which prevents displacement of the first bone member with respect to the second bone member in both a longitudinal direction and a transverse direction when an anatomical load is applied;

each bone member defining a bore within its body which is angularly oriented with respect to a plane across its mating face and opens on said mating face, each bore being axially aligned with an angularly oriented bore defined in the body of the other bone member and a cortical bone rod member having a partially demineralized outer surface mounted in said axially aligned bores extending across said mating face in an interference fit to hold the first and second bone members in engagement resisting separation of the first and second bone members.

Claim 30. A compound bone device made from sterile bone tissue for implantation into a surgical site which supports an anatomical load applied to the compound bone device during a post-operative period while the implanted bone tissue is being resorbed and remodeled, comprising:

a first bone member defining a first mating face constructed and arranged to support a load in a direction that is normal to the first mating face and to receive and engage a complimentary mating face of a second bone member;

a second bone member defining a second mating face that is complimentary to the first

mating face of the first bone member constructed and arranged to support a load in the direction normal to the second mating face, said mating faces being mounted to each other so that the first and second bone members form a compound bone device which prevents displacement of the first bone member with respect to the second bone member in both a longitudinal direction and a transverse direction when an anatomical load is applied;

each bone member defining a bore within its body which opens on said mating face, each bore being axially aligned with a similarly oriented bore defined in the body of the other bone member and a cortical bone rod member having a partially demineralized outer surface mounted in said axially aligned bores extending across said mating face in an interference fit to hold the first and second bone members in engagement resisting separation of the first and second bone members.

Claim 31. A compound bone device made from sterile bone tissue for implantation into a surgical site which supports an anatomical load applied to the compound bone device during a post-operative period while the implanted bone tissue is being resorbed and remodeled, comprising:

a first bone member defining a first mating face constructed and arranged to support a load in a direction that is normal to the first mating face and to receive and engage a complimentary mating face of a second bone member;

a second bone member defining a second mating face that is complimentary to the first mating face of the first bone member constructed and arranged to support a load in the direction normal to the second mating face, said mating faces being mounted to each other so that the first and second bone members form a compound bone device which prevents displacement of the first bone member with respect to the second bone member in both a longitudinal direction and a transverse direction when an anatomical load is applied;

each bone member defining a bore within its body which is angularly oriented with respect to a plane across its mating face and opens on said mating face, each bore being axially aligned with an angularly oriented bore defined in the body of the other bone member and a cortical bone rod member with a knurled outer surface mounted in said axially aligned bores extending across said mating face in an interference fit to hold the first and second bone members in engagement resisting separation of the first and second bone members.

Claim 32. A compound bone device made from sterile bone tissue for implantation into a surgical site which supports an anatomical load applied to the compound bone device during a post-operative period while the implanted bone tissue is being resorbed and remodeled, comprising:

a first bone member defining a first mating face constructed and arranged to support a load in a direction that is normal to the first mating face and to receive and engage a complimentary mating face of a second bone member;

a second bone member defining a second mating face that is complimentary to the first mating face of the first bone member constructed and arranged to support a load in the direction normal to the second mating face, said mating faces being mounted to each other so that the first and second bone members form a compound bone device which prevents displacement of the first bone member with respect to the second bone member in both a longitudinal direction and a transverse direction when an anatomical load is applied;

each bone member defining a bore within its body which is angularly oriented with respect to a plane across its mating face and opens on said mating face, each bore being axially aligned with an angularly oriented bore defined in the body of the other bone member and a wedge nail with an angular cross section press fit in said axially aligned bores and extending across said



mating face in an interference fit to hold the first and second bone members in engagement resisting separation of the first and second bone members.